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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,710	11/04/2003	Vinod Sharma	P-10314.00	7091

27581 7590 05/11/2005

MEDTRONIC, INC.
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EXAMINER

GREENE, DANA D

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 05/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/701,710

Applicant(s)

SHARMA ET AL.

Examiner

Dana D. Greene

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1-30-04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8-17, 19, and 27 stand rejected under 35 U.S.C. as being anticipated by Fox et al. (US 5,041,108, hereinafter "Fox"). Fox is considered to disclose:

an implantable medical device, comprising: an elongated body extending from a proximal end to a distal end engaged along a target site (see abstract, col. 7, ln. 59-65, and col. 8, ln. 64-68, Fox). The disclosed catheter and fibers are considered to anticipate the claimed implantable medical device because the catheter and fibers, like the claimed medical device, have a long and slender configuration with a proximal and distal end for contacting excitable body tissue after implantation in the body;

a delivery member extending through the elongated body to deliver a voltage sensitive dye outward from the distal end of the elongated body to the target site via the delivery member (see col. 7, ln. 59-65, Fox). The disclosed inflow channel is regarded as anticipatory in reference to the claimed delivery member because both carry fibers and dyes between the proximal and distal ends of the medical device;

a transmission member, extending through the elongated body, to transmit a signal associated with an action potential corresponding to the target site (see abstract,

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Fox). The disclosed fibers are considered to anticipate the transmission member (optical fiber) because both transmit signals or excitation light to the target tissue sites.

Claims 2 and 8-11 are not distinct over the Fox reference because Fox teaches a delivery member extending from a proximal end to a distal end capable of being advanced with a transmission member positioned within the delivery member (see col. 7, ln. 41-65 and col. 9, ln. 50-57, Fox). The disclosed inflow channel is considered to anticipate the delivery member as discussed above and is capable of holding a transmission member such as laser fiber bundles as taught in Fox (see col. 8, ln. 64-68, Fox).

With reference to claim 5, Fox is considered to disclose a transmission member formed as a helical coil (see col. 4, ln. 45-46, Fox). The disclosed optical fiber is considered to anticipate the claim helical coil because both configurations are designed to avoid fiber bending beyond a critical radius.

Referring to claims 12-17, Fox discloses an elongated body including an inner surface forming a first lumen, a positioning member, and an engaging member to fixedly position the positioning member (see col. 8, ln. 1-6, Fox). The disclosed elongate balloon establishes a fixed stabilized position and this is considered to anticipate the claimed engaging member because both work to stabilize lead position.

With reference to claims 19 and 27, Fox is considered to teach all of the elements as discussed above in addition to a means for generating a sense signal in response to the action potential being detected (see col. 9, ln. 14-17, Fox). The

disclosed laser is considered to anticipate the claimed means for generating sense signals because both produce a notification to a process of an event.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 6 is rejected under 35 U.S.C. §103(a) as being unpatentable over Fox in view of Shelton (US 5,836,989, hereinafter "Shelton"). Fox is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed intrinsic depolarization. Shelton teaches this depolarization (see col. 10, ln. 32-35, Shelton). The disclosed depolarization is considered to anticipate the claimed depolarization wave fronts because both affect the myocardial cells and the ventricular myocardium.

Referring to claim 7, Fox is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed plurality of

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electrodes. However, Shelton is considered to disclose the claimed plurality of electrodes for delivering therapy along the target site (see col. 9, ln. 9-14, Shelton). It would have been obvious to one of ordinary skill in the art to combine the teachings of Fox with the electrode configuration of Shelton for the purpose of monitoring the electrical activity and stimulating excitable body tissue.

With reference to claims 18, 20 and 28, Fox is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed means for determining intrinsic heart rate and inhibiting pacing output. However, Shelton is considered to disclose the claimed means for detecting intrinsic heart rate and inhibiting pacing output (see col. 2, ln. 5-10 and col. 9, ln. 35-40, Shelton). It would have been obvious to one of ordinary skill in the art to combine the teachings of Fox with the considered detecting means teaching found in Shelton for the purpose of accurate detection of heart rate in response to activation.

With reference to claims 21-26 and 29-34, Fox is considered to disclose the claimed invention as discussed above, under the anticipatory rejection except for the claimed means for performing a pacing threshold search. However, Shelton teaches this searching means (see col. 14, ln. 1-7, Shelton). It would be obvious to one of ordinary skill in the art to combine the teachings of Fox with pacing and monitoring modes taught in Shelton for the purpose of monitoring and detecting the pacing output in response to therapy delivery.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-7138. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-0276.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Dana D. Greene


George Manuel
Primary Examiner